#### IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

LIFEWATCH SERVICES, INC., and CARD GUARD SCIENTIFIC SURVIVAL, LTD.

Plaintiffs,

v.

BRAEMAR, INC., and ECARDIO DIAGNOSTICS, LLC

Defendants.

Civil Action No. 09-CV-6001

## DECLARATION OF ROBERT SCHWARZBERG

Honorable William J. Hibbler Magistrate Judge Arlander Keys

#### I, Robert Schwarzberg, do hereby declare:

- 1. I am the named inventor of Patent Number 5,730,143 (Electrocardiographic Monitoring and Recording Device) (the "143 Patent"). I formerly was the Chief Medical Officer of LifeWatch Services, Inc. ("LifeWatch"). I have been retained as an expert witness by the Defendants, Braemar, Inc. ("Braemar") and eCardio Diagnostics, LLC ("eCardio") in this matter.
- 2. I have been involved in cardiac monitoring and recording devices since 1988. Since 1986, I have been a board-certified cardiologist. My resume is attached as Exhibit A.
- 3. In the late 1980s, I was one of the principals in a company called Cardio Life. Cardio Life designed and manufactured looping and non-looping event recorders. While I was at Cardio Life, I developed an autotrigger loop recorder and invented the '143 Patent. I became the Chief Medical Officer of LifeWatch in about 1996 and held that position until the end of 2008. I have no continuing relationship with LifeWatch or its parent Card Guard Scientific Survival

Services, Inc. I now am the CEO of Sensei, Inc., which is involved in mobile applications for health and wellness.

- 4. Recently, I was contacted by LifeWatch's litigation counsel about this case. Until that point, I had not known that an infringement claim was pending against defendants. I declined to discuss the case with LifeWatch's litigation counsel. In late July, 2010, I contacted an old friend who now works at eCardio but who previously worked at LifeWatch, and inquired if he knew about the patent being enforced. He mentioned eCardio was a defendant. Counsel for eCardio then contacted me and asked if I would be an expert witness in the case to explain the technology in the '143 Patent.
- 5. I understand that a patent is to be interpreted as it would be understood by one of ordinary skill in the art. In this regard, I believe the relevant art is portable, wearable electronic devices for recording and transmitting electrocardiographic data. I believe a person of ordinary skill in the art would be an individual with experience in developing and/or designing cardiac monitors.
- 6. I have reviewed the '143 Patent. From my perspective as a person skilled in the art, what the invention of the '143 Patent did was to combine together a cardiac event recorder with a long term memory like that of a Holter monitor which has the capacity to record many hours of continuous electrocardiographic data recorded from the patient's heart rhythms ("ECG data").
- 7. As set forth in the specifications, the novelty in the '143 invention was combining together in one device the benefits one would gain from an event recorder, with the benefits one gains from having a record of long periods of continuous ECG data from the patient. In this way, the patient's medical team is alerted to arrhythmias, but also the medical team can see what

is happening during the intervals between the arrhythmia occurrences. The advantages of this combination are spelled out in Column 1 of the '143 Patent specifications.

- 8. As reflected in Figure 1 of the '143 Patent, the electrical signals from the heart are sent in parallel to two places an evaluation buffer and long-term storage. The long-term storage receives extended periods of continuous raw ECG data from the patient. It is long term in the sense of being measured by the many hours of ECG data (at least 12) that it records from the patient's heart.
- 9. I have read the LifeWatch brief filed in response to the motion of defendants for summary judgment. The assertion in the brief that "long term storage" in the '143 Patent means a medium for storing data for an extended period is not accurate. The "long" in long term storage refers to an amount of data measured by the length of time the data is collected, not how long the data is stored. In this instance, measurement of "long" by the amount of time and the amount of data are synonymous. At the same time, the medium on which the data is collected is a non-volatile memory, meaning it will survive if a loss of power occurs. Persistence of memory alone, however, would not have been a patentable concept, as persistence of memory was already well established in the field at the time of the invention of the '143 Patent. Nor would mere persistence of memory have any clinical significance, as it was the ability to view a continuous stream of ECG data over time that was key to the '143 patent.
- 10. In the '143 Patent, the other parallel path to which the electrical signals are transmitted is to the "event recorder" portion of the invention. There, the electric signals containing the ECG data flow through an evaluation buffer to be evaluated by a signal processing means which compares them to stored heart rhythm parameters to determine whether an arrhythmia has occurred. The evaluation buffer has a "loop" memory holding several minutes

of ECG data that constantly overwrites itself as the memory fills. If an arrhythmia occurs, the '143 Patent provides that the signal processing means will output an activation signal to cause the evaluation buffer to send the ECG data that is stored in its memory at the time of the activation signal to a holding buffer.

- 11. I have been informed that there is a dispute about the meaning of the term "long term storage" in claim 18 of the '143 Patent. Based on the stated purpose of the patent, the problems that it was meant to solve, the repeated references in the specifications to 12 to 24 hours of continuous data storage, Figure 1 and its accompanying discussions, and the language of the claim, it is my opinion that "long term storage" in claim 18 of the '143 Patent refers to the capability of extended memory reflecting longer recordings of continuous ECG data, i.e. storing 12 hours or more of ECG data of the patient. In support of this opinion, I rely not only upon my own experience in this art, but also express provisions of the '143 Patent, including the following:
- a. The statements of purpose in the patent ("an electrocardiographic monitoring and recording device that includes continuous long-term recording ..." Abstract); ("[T]his invention relates to a wearable device for the selective and continuous recording of electrocardiographic data." Column 1, lines 6-8).
- b. Statements in the patent with respect to the problems solved by the invention. (See generally the description of "background of the invention" in columns 1 and 2, and specifically the conclusion: "The present invention is directed to overcoming the shortcomings of both Holter type and event type cardiac monitors." Column 2, lines 7-9).
- c. The statements in the patent describing the invention: ("Simultaneously with the selective recording, continuous extending recording occurs, allowing for 24 hours or

more of ECG data to be captured for evaluation or all or any portion." Column 1, lines 13-16); ("The present invention is directed to an electrocardiographic monitoring or recording device that includes the continuous long-term recording of a Holter device and the selective recording of event type records." Column 2, lines 13-16); ("The monitor device of the present invention also includes a separate long-term memory for storing more data, hours before and/or after the trigger event, e.g., 12-24 hours or more of additional data, which can also be downloaded." Column 2, lines 31-34).

- d. The language of the claim 18 which describes a long-term storage means and expressly indicates that the signals stored are to be representative of the "heart rhythms of the patient . . ." Column 6, lines 57-58.
- e. Figure 1, which is the only figure attached to the patent and which specifically states that it is "constructed in accordance with the present invention." Column 2, lines 45-47. Figure 1 includes the "long term" storage in the Box labeled "22" and the specifications describe Box 22 as "the 12-24 hour long term memory 22 . . ." Column 4, lines 46-47.

I declare under penalty of perjury under the laws of the United States of America that the preceding is true and correct.

Robert Schwarzbe

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# **EXHIBIT A**

#### Robert J. Schwarzberg, M.D., F.A.C.C.

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### **Professional Experience**

Sensei, Inc. Boca Raton, Florida President and Chief Executive Officer September, 2005 - Present

- Created concept and business plan
- Responsible for strategic planning, content and P/L management.
- Instrumental in identifying and forging partnership with Humana
- Sensei is developing health and wellness applications for Mobile Phones

## Cardguard AG Zurich, Switzerland

November, 2004 - 2008

Chief Medical Officer (Boca Raton, FL)

- -Product development and applications
- -Strategic planning
- -Strategic relationships

### LifeWatch, Inc. Buffalo Grove, Illinois Medical Director (Boca Raton, FL)

May, 1999 - 2008

- -Strategic development
- -Chairman of Medical Advisory Board
- -Supervision and quality assurance for all clinical departments
- -Consult with physician customers.

Ralin Medical, Inc. Buffalo Grove, Illinois Chief Medical Officer (Boca Raton, FL)

October, 1996 - December, 1999

Ralin Medical was the parent company for Cardiac Solutions (now CorSolutions), national leader in disease state management and LifeWatch, the industry leader in cardiac arrhythmia monitoring.

- -Disease State Management Programs- Collaborated on completing, updating and enhancing details of CHF, Diabetes, and CVD programs.
- -Collaborated in development and introduction of COPD program.
- -Designed and implemented program to enhance physician compliance with guidelines demonstrated 200% improvement.
- -Developed the financial model based on clinical impact for CVD program culminating in several contracts including 2 of the nations largest mco's.

- -Identified and recruited group of experts for completion of COPD program.(at 15% of cost of our other disease management programs.)
- -Identified and recruited array of experts for national advisory board.
- -U.S. Patent awarded for new cardiac arrhythmia monitor. Negotiations are underway with device manufacturers for this device

## Primus Health Plan Miami, Florida

1995 - 1996

General Partner, Board of Directors

Start up company attempting to develop physician owned managed care company.

## CardioLife Corporation Boca Raton, Florida

1989 - 1996

Chairman and Medical Director

- -Supervision and Quality Assurance for all clinical departments.
- -Consultant to physician customers.
- -Development of clinical guidelines
- -Director of Medical Advisory Board
- -Manage product development.
- -Defined new monitor specifications, successfully negotiated with device manufacturer for production at lowest market price in industry. Initial units delivered within 120 days of signed contract and restricted sales to third parties.

## Robert J. Schwarzberg, M.D., P.A. Boca Raton, Florida Cardiologist

1988 - Present

Private Practice of Cardiology

## Kaplan, Jaffe and Shine, P.A. Miami Beach, Florida

1986 - 1988

Cardiologist

Private Practice of Cardiology

## **Appointments**

#### American College of Cardiology

2003 - Present

National Disease Management Working Group

January 2004 - Present

Medical Director Institute

2003 - Present

Consensus Work Group on Disease Management (Chicago, Il	II.) June 2003
American College of Cardiology, Florida Chapter Third Party Reimbursement Group	2003 - Present
Microsoft Consultant Health Care Strategy Group	2006
Humana Inc. Louisville, KY National Medical Consultant Group	January 2000 – 2001
Boca Raton Community Hospital Boca Raton, Florida Hospital Quality Council, Chairman	2000 - 2001 January 2000 - 2001
Heart Failure Taskforce, Chairman	January 2000 - 2001
Cardguard Scientific Survival Rehovot, Israel Medical Advisory Board	September, 1999 - Present
Florida Atlantic University Boca Raton, Florida Clinical Associate Professor of Biomedical Science	September 1999 - Present
American Heart Association Boca Raton, Florida Board of Directors	September 1998 - Present
Education	
Long Island Jewish Medical Center New Hyde Park, New Fellow in Clinical Cardiology	York 1984 - 1986
Columbia Presbyterian Hospital New York, New York Fellow in Nuclear Cardiology	1984
The Mount Sinai Hospital New York, New York Junior Assistant Resident in Internal Medicine	1982 - 1983 1982
Senior Assistant Resident in Internal Medicine	1983
George Washington University Hospital Washington, D.C. Intern in Internal Medicine	1981
Wayne State University School of Medicine Detroit, Michig Graduated as Doctor of Medicine	gan 1980
Columbia College, Columbia University New York, New Y	7ork 1974

#### Graduated with Bachelor of Arts

### **Membership**

American College of Cardiology American Heart Assocation Disease Management Association Mobile Marketing Association Society of Behavioral Medicine Behavior Informatics Group

#### License

Florida Medical License, 1986: #48642

Diplomat, American Board of Internal Medicine in the Subspecialty of Cardiovascular Disease, 1985

License in Nuclear Cardiology, 1984

Diplomat, American Board of Internal Medicine, 1983

New York State Medical License, 1981: #146543